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Indian Standard

SPECIFICATION FOR ZINC OXIDE SELF-ADHESIVE PLASTER

(First Revision)

UDC : 615.468·292 : 661.847·12

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INDIAN STANDARDS INSTITUTION
MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG
NEW DELHI 110002

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AMENDMENT NO. 4 OCTOBER 2000
TO
IS 4717 : 1980 SPECIFICATION FOR ZINC OXIDE SELF-ADHESIVE PLASTER

(First Revision)

[*Page* 11, *Appendix* D, *clause* D-4.1.3, *line* 2 (see also Amendment No. 2)] — Insert the following after the word 'Steel plate' :

'at the separation speed of 305±13 mm per minute'.

(MHD 15)

Reprography Unit, BIS, New Delhi, India

AMENDMENT NO. 2 JANUARY 1992
TO
IS 4717 : 1980 SPECIFICATION FOR ZINC OXIDE SELF - ADHESIVE PLASTER

(First Revision)

(*Page* 5, *clause* 4.2, *line* 2) — Substitute 'method specified in Appendix XXQ of B.P 1988, Vol II (p. A227)' *for* 'Appendix B'.

(*Page* 5, *clause* 5.1, *line* 3) — Substitute 'Appendix B' *for* 'Appendix C'.

(*Page* 5, *clause* 5.2.1, *line* 3) — Substitute 'Appendix C' *for* 'Appendix D'.

(*Page* 5, *clause* 5.2.2, *line* 3) — Substitute 'Appendix D' *for* 'Appendix E'.

(*Pages* 7, 8 *and* 9, *Appendix* B) — Delete.

(*Page* 9, *Appendix* C) — Redesignate it as 'Appendix B' and renumber the subsequent clauses.

(*Pages* 10, 11 *and* 12, *Appendix* D) — Redesignate it as 'Appendix C' and renumber the clauses accordingly.

(*Page* 10, *new clause* C-2.3, *line* 1) — Substitute 'minimum 80 mm diameter' *for* '80 ± 2 mm diameter'.

(*Pages* 12 *and* 13, *Appendix* E) — Redesignate it as 'Appendix D' and renumber the clauses accordingly.

(*Amendment No.* 1) — Substitute 'Appendix E' *for* 'Appendix F' and 'clause D-5.1' *for* 'clause E-5.1'.

(*Amendment No.* 1, *Appendix* F) — Renumber the clauses accordingly.

(MHD 15)

Reprography Unit, BIS, New Delhi, India

AMENDMENT NO. 1 NOVEMBER 1984

TO

IS:4717-1980 SPECIFICATION FOR ZINC OXIDE SELF-ADHESIVE PLASTER

(First Revision)

(*Page 6, clause 7.3*) - Add the following new clauses after 7.3:

'8. SAMPLING

8.1 The sampling plan and criteria for conformity shall be in accordance with Appendix F.'

(*Page 13, clause E-5.1*) - Add the following new Appendix after E-5.1:

"APPENDIX F
(*Clause* 8.1)

SAMPLING PLAN AND CRITERIA FOR CONFORMITY

F-1. LOT

F-1.1 In any consignment, all spools of zinc oxide self-adhesive plaster of similar size produced under similar conditions shall constitute a lot.

F-1.2 The number of spools to be selected from each lot shall depend upon the size of the lot and shall be in accordance with col 1 and 2 of Table 2.

TABLE 2 SAMPLE SIZE AND CRITERIA FOR CONFORMITY

LOT SIZE (1)	*SAMPLE SIZE* (2)	*ACCEPTANCE NUMBER* (3)
Up to 300	13	1
301 to 500	13	1
501 " 1000	20	2
1001 " 3000	32	3
3001 " 10000	32	3
10001 " 35000	50	5
35001 and above	80	7

F-1.2.1 These spools shall be selected from the lot at random and in order to ensure the randomness of selection, procedures given in IS:4905-1968 'Methods for random sampling' shall be adopted.

F-2. NUMBER OF TESTS AND CRITERIA FOR CONFORMITY

F-2.1 The number of spools selected at random in accordance with col 2 of Table 2 shall be tested for dimensions (*see* 3.1). The lot shall be considered as conforming to this requirement if the number of defectives found in the sample is less than or equal to the corresponding acceptance number of defectives as given in col 3 of Table 2.

F-2.2 If the lot is conforming to the requirements as mentioned in F-2.1, the ltest for weight of adhesive mass, zinc oxide content, tensile strength of plaster and adhesion property (*see* 4.1, 4.2, 5.1 and 5.2), shall be carried out. The number of times each test is to be repeated shall be in accordance with col 1 and 2 of Table 3. If the sample passes each number of times, the lot shall be considered as conforming to these tests.

TABLE 3 NUMBER OF TIMES THE TEST IS TO BE REPEATED FOR MANUFACTURE AND PERFORMANCE REQUIREMENTS

LOT SIZE (1)	*NO. OF TIMES EACH TEST IS TO BE REPEATED* (2)
Up to 500	1
501 to 1000	2
1001 " 3000	3
3001 " 10000	4
10001 and above	5

F-2.3 The lot shall be considered as conforming to the requirements of this standard if F-2.1 and F-2.2 are satisfied."

(CPDC 19)

Indian Standard

SPECIFICATION FOR ZINC OXIDE SELF-ADHESIVE PLASTER

(*First Revision*)

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(*Continued on page* 2)

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(*Continued from page* 1)

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Indian Standard

SPECIFICATION FOR ZINC OXIDE SELF-ADHESIVE PLASTER

(First Revision)

0. FOREWORD

0.1 This Indian Standard (First Revision) was adopted by the Indian Standards Institution on 15 February 1980, after the draft finalized by the Surgical Dressings Sectional Committee had been approved by the Consumer Products and Medical Instruments Division Council.

0.2 This standard was first published in 1968. Since then many suggestions were received for improvement. This standard is being revised to incorporate the suggestions received from time to time.

0.3 Zinc oxide self-adhesive plaster consists of a suitable cloth, coated uniformly on one side with a pressure sensitive adhesive mass containing zinc oxide. It is used to secure dressings, protect wounds and to immobilise small areas.

0.4 This standard contains clause **3.1** which calls for agreement between the purchaser and the supplier regarding dimensions.

0.5 For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the results of a test or analysis, shall be rounded off in accordance with IS : 2-1960*. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

1. SCOPE

1.1 This standard covers requirements pertaining to material, construction and performance of zinc oxide self-adhesive plaster.

---

*Rules for rounding off numerical values (*revised*).

2. MATERIAL

2.1 Cloth — The cloth shall be plain woven and made of cotton or mixture of cotton and rayon. The blend shall not have more than 25 percent rayon when tested by the method given in IS : 1889 (Part I)-1976*.

2.1.1 The cloth shall be reasonably free from spinning, weaving and processing defects. It shall be finished to a good white colour or dyed to flesh colour with a suitable non-toxic dye. The basic cloth shall conform to the particulars given in Table 1.

TABLE 1 MANUFACTURING PARTICULARS OF BASIC CLOTH

PARTICULAR (1)	REQUIREMENT (2)	METHOD OF TEST, REF TO (3)
Ends per dm, *Min*	250	IS : 1963-1969*
Picks per dm, *Min*	225	
Weight, g/m^2, *Min*	120	Appendix A

*Methods for determination of threads per decimetre in woven fabrics (*first revision*).

2.2 Self-Adhesive Material — Self-adhesive mass shall contain zinc oxide of I.P. grade.

3. DIMENSIONS

3.1 The dimensions of the plaster shall be agreed to between the purchaser and the supplier. Recommended sizes are as follows:

Width mm	*Length* m
12·5	1, 5
25	1, 5, 10
50	5, 10
75	5, 10
100	5, 10

---

*Method for quantitative chemical analysis of binary mixtures of regenerated cellulose fibres and cotton: Part I Sodium zincate method (*first revision*).

3.1.1 The length shall be not less than 99·5 percent of the declared length. The width shall be within the following tolerances:

Nominal Width mm	*Tolerance* mm
Up to 25	± 1·0
Over 25 up to 50	± 1·5
Over 50	± 2·0

4. MANUFACTURE

4.1 Weight of Adhesive Mass — Weight of adhesive mass shall be not less than 115 g/m^2 when determined according to Appendix A.

4.2 Zinc Oxide Content — Zinc oxide content of the adhesive mass shall be not less than 10 percent when tested according to Appendix B.

5. PERFORMANCE REQUIREMENTS

5.1 Tensile Strength of Plaster — The plaster shall have a tensile strength of not less than 8 kgf/cm width along the warp when determined by the method given in Appendix C.

5.2 Adhesion Property

5.2.1 *Adhesion to Metal* — The adhesion strength of plaster to metal shall be not less than 200 gf/cm width when tested according to the method given in Appendix D.

5.2.2 *Adhesive Strength* — The adhesive strength shall be not less than 7 kgf cm width when tested according to the method given in Appendix E.

6. TESTS

6.1 Tests for various requirements shall be conducted as prescribed in appropriate appendices and relevant clauses of this standard.

6.2 Conditioning — Each roll selected for test shall be conditioned for a minimum period of 24 hours at 27 ± 2°C and 65 ± 5 percent relative humidity (*see* IS : 196-1966*) prior to testing, and the testing shall be conducted in the same atmosphere. Where the tests cannot be carried out in the same atmosphere, the testing shall be commenced within 2 minutes of withdrawal of the specimen from the conditioning atmosphere.

---

*Atmospheric conditions for testing (*revised*).

6.3 Three outer layers of each roll shall be discarded before taking specimen for test.

6.4 All specimens shall be removed from the roll at an approximate speed of 30 cm/min.

6.5 The adhesive surface shall not be permitted to come in contact with the fingers, to be contaminated with dust, or to come in contact with any other foreign matter.

7. PACKING AND MARKING

7.1 The adhesive plaster shall be uniformly and evenly wound on suitable spools. These spools shall be packed in suitable containers so that it is adequately protected from dust, damage in transportation and from deterioration due to climatic conditions.

7.2 Each spool and container or both shall be marked with the following information:

a) Name and type of the plaster,

b) Manufacturer's name and recognized trade-mark,

c) Dimensions of the plaster,

d) Manufacturing licence number of the manufacturer,

e) Batch number,

f) Month and year of manufacture, and

g) Directions for storage and use.

7.3 Each spool or container or both may also be marked with the ISI Certification Mark.

NOTE -- The use of the ISI Certification Mark is governed by the provisions of the Indian Standards Institution (Certification Marks) Act and the Rules and Regulations made thereunder. The ISI Mark on products covered by an Indian Standard conveys the assurance that they have been produced to comply with the requirements of that standard under a well-defined system of inspection, testing and quality control which is devised and supervised by ISI and operated by the producer ISI marked products are also continuously checked by ISI for conformity to that standard as a further safeguard. Details of conditions under which a licence for the use of the ISI Certification Mark may be granted to manufacturers or processors, may be obtained from the Indian Standards Institution.

APPENDIX A

(*Clause* 4.1, and *Table* 1)

METHOD FOR DETERMINATION OF WEIGHT OF FABRIC AND WEIGHT OF ADHESIVE MASS

A-1. TEST SPECIMEN

A-1.1 Cut about 10 g of the plaster from the sample and weigh accurately. Take care to cut parallel to the edges of the plaster.

A-2. PROCEDURE

A-2.1 Measure the area of the specimen accurately and extract with chloroform in a Soxhlet extractor until the adhesive mass completely disintegrates Take out the fabric, dry to remove residual chloroform and immerse in dilute acetic acid for 3 hours. Remove sample in a suitable vessel and wash 12 times with boiling water, using 1 000 ml for each washing. Pass wash waters through 150-micron IS sieve to collect any loose fibre or yarn Dry the residue to constant weight at 100 ± 2°C and correct the weight for moisture regain.

A-2.2 Calculate the weight of fabric in grams per square metre. Calculate the weight of the adhesive mass in grams per square metre by subtracting the weight of the fabric from the weight of sample originally taken, as given below.

$$\text{Weight of adhesive mass} = \frac{W - w}{A} \text{ g/m}^2$$

where

W = weight in grams of the sample taken,

w = weight in grams of the residual fabric corrected for moisture regain, and

A = area in square metres of the sample taken.

NOTE — Moisture regain = 8 53 percent.

APPENDIX B

(*Clause* 4.2)

METHOD FOR DETERMINATION OF ZINC OXIDE CONTENT

B-1. REAGENTS

B-1.1 Nitric Acid — *See* IS : 264-1976*.

---

*Specification for nitric acid (*second revision*).

B-1.2 Dilute Ammonium Hydroxide — approximately 6 N.

B-1.3 *p*H 10 Buffer — Dissolve 68 g of ammonium chloride in 200 ml of water, add 570 ml of concentrated ammonia, and dilute to 1 litre.

B-1.4 Eriochrome Black T Indicator — Dissolve 0·2 g of the dye and 2 g of hydroxylamine hydrochloride in 50 ml of methanol.

B-1.5 Standard EDTA Solution — Dry ethylenediamine tetra-acetate dihydrate disodium salt (EDTA) at 80°C and a relative humidity of 50 percent (25°C) for a period of 2 to 3 days to give a product approaching 100 percent in assay. Dissolve about 3·8 g of EDTA in 500 to 800 ml of water in a 1 000 ml volumetric flask. When solution is complete, dilute to the mark and mix thoroughly. Transfer the solution to a polyethylene bottle. This solution is approximately 0·01 M. Standardize this solution with standard calcium chloride solution. Calculate the exact strength of EDTA solution. Carry out the operations as in **B-1.5.1** and **B-1.5.2**.

B-1.5.1 *Using GBHA [Glyoxal bis (2-hydroxy-anyl)] Solution* — Transfer 25 ml of the standard calcium solution to a 250-ml erlenmeyer flask. Add about 25 ml of water. Add by means of graduated pipettes, 4 ml of sodium hydroxide solution, 15 ml of ethanol and 1 ml of GBHA indicator solution. Allow it to stand for about 2 minutes. Titrate with EDTA until colour turns from red to pure yellow.

B-1.5.2 Prepare colour comparison blanks by successively transferring to 250-ml conical flasks, approximately the same amount of water, the reagents, the indicator and sufficient EDTA to produce an unchanging colour.

B-2. PROCEDURE

B-2.1 Cut from the sample under test two specimens weighing 1 g each taking as much care as possible to cut parallel to the warp and weft threads Take one specimen and find the weight of adhesive mass as in Appendix A. Heat the second specimen with 10 ml of nitric acid in a round bottom flask until the plaster disintegrates. Boil it for 10 to 15 minutes on a low flame. Cool and dilute with 10 to 15 ml of water and add one or two drops of methyl red indicator Neutralize using dilute ammonia solution. Add 20 ml of *p*H buffer and 2 drops of eriochrome black T indicator to obtain a clear visible red colouration in the solution. Titrate it with EDTA solution until the colour changes from red to blue.

B-3. CALCULATION

B-3.1 Zinc oxide (as ZnO), percent by weight $= 8{\cdot}138 \times \frac{V \times M}{W}$

where

V = volume in ml of EDTA solution used for titration,
W = weight in grams of the adhesive mass, and
M = molarity of EDTA solution used for titration.

APPENDIX C

(*Clause* 5.1)

METHOD FOR DETERMINATION OF TENSILE STRENGTH

C-0. OUTLINE OF THE METHOD

C-0.1 Breaking strength is determined by finding the load at which the tape breaks, when tested on a tensile strength testing machine.

C-1. NUMBER OF TESTS

C-1.1 Carry out the determinations on three test specimens taken from the same roll.

C-2. APPARATUS

C-2.1 Tensile Testing Machine — A suitable tensile testing machine.

C-3. CONDITIONING

C-3.1 Condition the rolls as specified in **6.2** and take all the precautions as specified in **6.3** to **6.5** for taking the test specimen.

C-4. PROCEDURE

C-4.1 Take test specimen of sufficient length to accommodate in a jaw separation of 12 cm and measure its width. Clamp the strip of plaster squarely in the jaws of the tensile testing machine. Note the load at break. Reject the pieces breaking within 5 mm of the edge of the jaws. Repeat the test.

C-5. CALCULATION AND REPORTING

C-5.1 The mean of the three determinations shall be taken as the breaking strength in kilograms per centimetre width.

APPENDIX D

(*Clause* 5.2.1)

METHOD FOR DETERMINATION OF ADHESION TO METAL

D-0. OUTLINE OF THE METHOD

D-0.1 Adhesion to metal is determined by finding the force required to peel a strip of tape from a standard test panel at a specified angle and speed.

D-1. NUMBER OF TESTS

D-1.1 Carry out the determination of 5 test specimens taken from the same roll.

D-2. APPARATUS

D-2.1 Tensile Testing Machine — A suitable tensile testing machine.

D-2.2 Stainless Steel Plates — Rectangular, 10 × 30 cm polished stainless steel plates.

D-2.2.1 The stainless steel plates shall have a standard abrasive satin finish (180 grit) with the direction of gritting lying parallel to the longer side of the plate.

D-2.2.2 The stainless steel plates shall also be marked boldly or etched at intervals of 2 cm along both the longitudinal edges.

D-2.3 Roller — A steel roller of 80 ± 2 mm diameter and 45 ± 1 mm in width covered with rubber approximately 6 mm thick having a hardness of 80 ± 5 IRHD. The weight of the roller which applies pressure to the specimen shall be 2·05 ± 0·05 kg. It shall be so constructed that the weight of the handle is not added to the weight of the roller during use (*see* Fig. 1).

D-3. PREPARATION OF TEST SPECIMEN

D-3.1 Condition the rolls as specified in **6.2** and take all precautions as specified in **6.3** to **6.5** for taking the test specimen. Test specimen shall be 0·5 to 3 cm in width and not less than 50 cm in length. If the width of the tape is greater than 3 cm, then reduce it to 3 cm by cutting it with a sharp blade.

D-4. PROCEDURE

D-4.1 Adhesion to Metal

D-4.1.1 Clean thoroughly the surface of the stainless steel plate with redistilled toluene using a fresh piece of untreated paper tissue or cotton wool for each cleaning. When all the solvent has evaporated, wipe the surface with a piece of clean dry tissue paper or cotton wool, taking precautions not to touch the steel plate with the fingers. Apply at least 25 cm of test specimen without stretching, keeping adhesive side down, to the centre of surface of the steel plate and parallel to the longer side, leaving the remainder of the test specimen extending beyond the steel plate sufficient to be accommodated in the testing equipment. Precaution shall be taken that no air bubbles are trapped between the tape and the plate

NOTE -- In the case of tapes less than 3 cm width, cut other strips from the same sample roll and apply them parallel and adjacent to the test specimen to provide a total width of 3 cm for rolling purposes only.

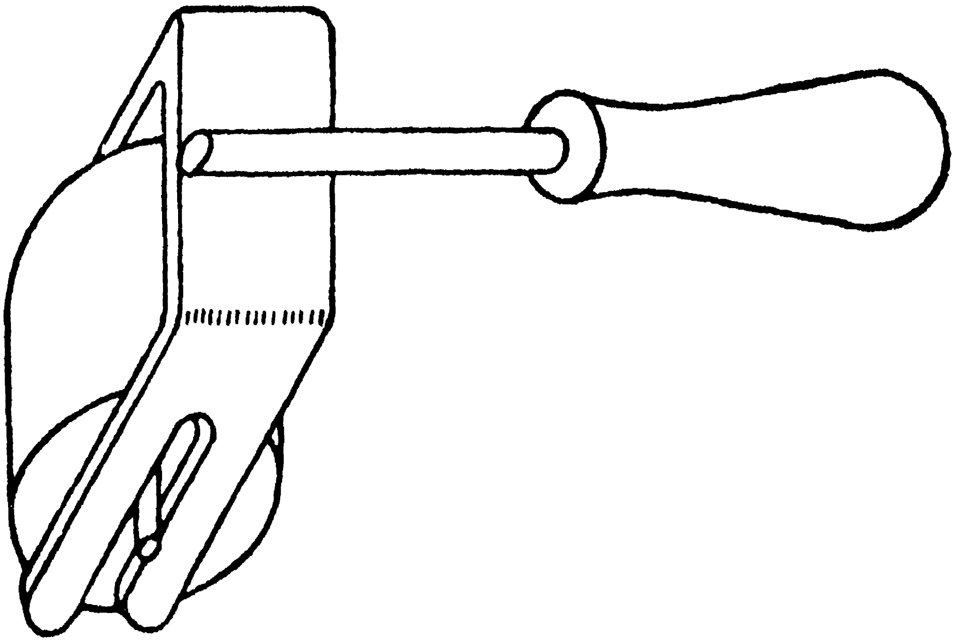

FIG. 1 ROLLER

D-4.1.2 Place the roller centrally across the test specimen at one end of the plate and pass the roller once in each direction at constant speed of approximately 30 cm/min, ensuring that no additional pressure of the weight of the roller is applied during the process. Allow the steel plate with the test specimen to remain undisturbed for 10 ± 0·5 min at a temperature of 27 ± 2°C and 65 ± 5 percent relative humidity.

D-4.1.3 Fold the free end of the test specimen at an angle of 180° and peel off 3 cm from the steel plate leaving at least 22 cm in contact with the steel plate. Clamp this exposed end of the plate in the lower jaw (if using a vertical pendulum or spring balance type machine), or attach the whole plate to the moving carriage (if the testing machine is of the horizontal type). Attach the free end of the tape to the head of the tension measuring device and disengage the pawls, if any. Start the tensile testing machine and take readings at 2 cm intervals when the tape is pulled from the steel plate, disregarding the pulling of first 5 cm and last 3 cm. The mean of 5 readings shall give the load required to cause the separation of the tape from the steel plate. If the specimen breaks during the test, repeat the test on another specimen cut from the same roll.

D-5. CALCULATION AND REPORTING

D-5.1 Calculate the load required to cause the separation of the tape from the steel plate (or from a piece of tape itself as the case may be), in terms of grams per centimetre of width. The mean of 5 values obtained shall be reported as adhesion strength.

APPENDIX E

(*Clause* 5.2.2)

METHOD FOR DETERMINATION OF ADHESIVE STRENGTH

E-0. OUTLINE OF THE METHOD

E-0.1 Adhesive strength is determinated by finding the force required to peel or break a strip of tape from a standard test panel at a specified angle and speed.

E-1. NUMBER OF TESTS

E-1.1 Carry out the determination of 5 test specimens taken from the sample roll.

E-2. APPARATUS

E-2.1 Tensile Testing Machine same as the one described in **D-2.1**.

E-2.2 Plastic or Glass Plates

E-2.3 Roller — A rubber roller which applies 850 g pressure to the specimen. It shall be so constructed that the weight of the handle is not added to the weight of the roller during use (*see* Fig. 1).

E-3. PREPARATION OF TEST SPECIMEN

E-3.1 Take all precautions as specified in **6.3** to **6.5** for taking the test sample. The test specimen shall be 2·5 cm in width and 15 cm in length. If the width of the tape is greater than 2 5 cm, reduce it to 2·5 cm by cutting it with a sharp blade.

E-4. PROCEDURE

E-4.1 Adhesive Strength

E-4.1.1 Clean the surface of the glass or plastic plate thoroughly with toluene. When all the solvent has evaporated, wipe the surface with a piece of clean dry tissue paper or cotton wool.

E-4.1.2 Apply 2·5 cm by 5 cm of one end of the test specimen to the plastic/glass plate without stretching, keeping adhesive side down, to the centre of the plate, and leaving the remainder of the test specimen extending beyond the plate. Precautions should be taken not to entrap any air bubbles between the tape.

E-4.1.3 Place the roller centrally across the test specimen and draw the roller once in each direction at constant speed of about 30 cm/min.

E-4.1.4 Adjust the temperature of the plastic or glass plate surface and the tape to 37°C and conduct the test within two minutes.

E-4.1.5 Clamp the specimen in the jaws of the tensile strength machine. The jaws are about 10 cm apart at the beginning of the test. Start the machine. Read the load at break or maximum load in case of peel off on the sealer. Discard the specimen breaking near the edge of the jaws, repeat the test.

E-5. CALCULATION AND REPORTING

E-5.1 Calculate the load required to cause break or pull-off of the tape in terms of 9 cm of width. The mean of five values obtained shall be reported as adhesive strength.

INTERNATIONAL SYSTEM OF UNITS (SI UNITS)

Base Units

Quantity	Unit	Symbol
Length	metre	m
Mass	kilogram	kg
Time	second	s
Electric current	ampere	A
Thermodynamic temperature	kelvin	K
Luminous intensity	candela	cd
Amount of substance	mole	mol

Supplementary Units

Quantity	Unit	Symbol
Plane angle	radian	rad
Solid angle	steradian	sr

Derived Units

Quantity	Unit	Symbol	Definition
Force	newton	N	1 N = 1 kg.m/s^2
Energy	joule	J	1 J = 1 N.m
Power	watt	W	1 W = 1 J/s
Flux	weber	Wb	1 Wb = 1 V.s
Flux density	tesla	T	1 T = 1 Wb/m^2
Frequency	hertz	Hz	1 Hz = 1 c/s (s^{-1})
Electric conductance	siemens	S	1 S = 1 A/V
Electromotive force	volt	V	1 V = 1 W/A
Pressure, stress	pascal	Pa	1 Pa = 1 N/m^2

AMENDMENT NO. 3 MAY 1993
TO
IS 4717 : 1980 SPECIFICATION FOR ZINC OXIDE SELF - ADHESIVE PLASTER

(First **Revision)**

(***Page*** 4, *Table* 1, ***col*** 3) — Substitute 'IS 1963 :1981*' for 'IS 1963 1969*'.

(***Page*** 4, ***Table*** '1, ***foot-note*** *marked with '*' mark*) — Substitute the **following** for the existing foot-note:

'***Methods** for **determination** of threads *per unit* length in woven fabrics (*second revision*).'

[*Page* 10, ***clause*** C-2.3, line 4 (see ***also*** Amendment No. 2)] — Substitute '**2.05** ± *0.05 kg*' *for* '205 ± 0.05 kg'.

(MHD 15)

Reprography Unit, BIS, New Delhi, India

PUBLICATIONS OF INDIAN STANDARDS INSTITUTION

INDIAN STANDARDS

Over 10 000 Indian Standards covering various subjects have been issued so far. Of these, the standards belonging to the Consumer Products and Medical Instruments Group fall under the following categories:

Anaesthesia, resuscitation and allied equipment
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